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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,315	01/09/2001	Jeremy Carver	14096.15USWO	8757
23552 7590 06/20/2007 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER EPPERSON, JON D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/701,315	Applicant(s) CARVER ET AL.	
	Examiner Jon D. Epperson	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7-17 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 2, 3 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants response filed March 28, 2007 is acknowledged

Status of the Claims

2. Claims 1-22 were pending.
3. Applicant's election of Group I (claims 1-6 and 18-22) without traverse (e.g., see 5/13/02 Response) is acknowledged and claims 7-17 are withdrawn from consideration.
4. Please note: Applicant's *specifically* elected species (10/26/06 Response) was searched and was not found in the prior art. Thus, the search was expanded to non-elected species (see rejections below). See MPEP § 803.02.
5. Claims 20-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species, the requirement having been traversed in the 10/26/05 Response (see below). Although Applicants have stated that claims 1-6 and 18-22 read on the elected species, this was in error. For example, Formula A on page 2 of the 10/26/06 Response shows that X = hydrogen. However, claims 20-22 contain X = COOH, OSO₃H, or CH₂qSO₃H. Thus, X = hydrogen does not read on claims 20-22 as erroneously reported. In addition, claims 20-22 do not contain the elected "capping" group and thus do not read on the elected invention (e.g., compare claims 20-22 to claim 19 which reads, "wherein free amino groups are protected with a cap monomer").

6. Therefore, claims 1-6, 18, and 19 are examined on the merits in this action.

Response to Election of Species Traversal

7. Applicant's election of species with traverse is acknowledged.

8. The traversal found to non-persuasive and is addressed below:

[1] Applicants argue, "the inventive concept is independent of any particular core structure" (e.g., see 10/26/06 Species election, page 2).

[1] The species are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j); see also 806.04(f). In the instant case, the species are distinct because they have different core structures and thus would require a materially different design. Furthermore, the species as are not mutually exclusive and there is nothing of record to show them to be obvious variants. For example, a compound with X = COOH would not anticipate a compound with X = OSO₃H. Furthermore, nothing of record shows that X = COOH is an obvious variant of COOH or any of the other listed Markush members. Thus, the inventive concept is not independent of the core structure.

[2] Applicants argue, "libraries can readily be searched with any particular core structure" (e.g., see 10/26/06 election, page 3, paragraph 1).

[2] The Examiner respectfully disagrees. Each position (e.g., X, R, Z', Z, Y, etc.) on the

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structure shown in formula I can be independently varied which would lead to an enormous number of possibilities. Thus, the searches would not be co-extensive. Searching $X = \text{COOH}$ would not lead to art on $X = \text{OSO}_3\text{H}$ for example. Thus, an undue search burden has been shown for both the patent and non-patent literature.

9. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Specification

10. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time

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period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Objections to the Claims

11. Claims 2, 3, and 6 are objected to because of the following informalities:

A. Claim 2 recites "I, II, II, IV or V" in line 2. Removal or correction of the second "II" is requested. In addition, claim 2 recites " β 1,6-N-acetylglucosaminyl transferase" without a "-" between the β and the 1. A comma also appears to be missing between β -1,3-galactosyl-O-glycosyl-glycoprotein and β -1,6-N-acetylglucosaminyl transferase. Correction is requested.

B. Claim 3 recites 5' amino-5' deoxy-2',3'-O-isopropylidene uridyl without a "-" between the 5' and the deoxy. Correction is requested.

C. Claim 3 recites, "carbohydrate processing enzyme is an N-acetylglucosaminyltransferase I, II, II, IV or V" in line 2. The second "II" appears to be a typographical error. Correction is requested.

D. Claim 6 recites, "single amide lined amino acid" in line 2. The examiner recommends using the original "linked" spelling. Correction is requested.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-6, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. **Claim 1** recites the limitation "the transfer of a sugar" in line 2. There is insufficient antecedent basis for this limitation in the claim. Therefore, claim 1 and all dependent claims are rejected under 35 USC 112, second paragraph.

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B. **Claim 19** recites improper Markush format. For example, claim 19 reads “R⁴ is phenyl-R⁵ ... or N(CH₃(CH₂)CH₂R⁶ ... or R⁴ represents (CH₂)_nR⁸.” The term “or” must only be used once and the phrase “selected from the group consisting of” is also proper as outlined below. It is suggested to use standard Markush language; see MPEP 2173.05(h) concerning alternative expressions:

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being “selected from the group consisting of A, B and C.” See *Ex parte Markush*, 1925 C.D. 126 (Comm’r Pat. 1925).

When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if “wherein R is a material selected from the group consisting of A, B, C and D” is a proper limitation, then “wherein R is A, B, C or D” shall also be considered proper.

Therefore, claims 19 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

C. **Claim 5** recites the limitation “the cap monomer” in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. For example, claim 1, from which it depends, recites, “cap monomers” in line 6. Thus, it is unclear whether “all” of the monomers must possess the recited Markush listing or some small portion of the total. Therefore, claim 5 and all dependent claims are rejected under 35 USC 112, second paragraph.

D. For **claims 1, 6, and 18**, the term “amino acid” has been defined in the specification to encompass molecules that are repugnant to that term (e.g., see specification, page 6, last two paragraphs). While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The

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term "amino acid" in claim 1, 6 and 8 is used by the claim to mean a wide range of compounds including "esters" that do not contain an acid moiety, while the accepted meaning is "a compound with the formula $\text{NH}_2\text{CHR}\text{COOH}$ " (e.g., see Wikipedia, the Free Encyclopedia. Amino Acid. Retrieved at on June 7, 2008 from http://en.wikipedia.org/wiki/Amino_acid, page 1 of 11). Therefore, claims 1, 6, 18 and all dependent claims are rejected under 35 U.S.C. § 112, second paragraph.

Claims Rejections - 35 U.S.C. 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-6, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shenbagamurthid et al.

(Shenbagamurthid et al., "Synthesis and Biological Properties of Chitin Synthetase Inhibitors Resistant to Cellular Peptidases" *J. Med. Chem.* **1986**, 29, 802-809) as evidenced by Spindler et al. (e.g., see Spindler et al., "chitin metabolism: a target for drugs against parasites" *Parasitol Res* **1990**, 76, 283-288).

For *claims 1-3*, Shenbagamurthi et al. teach a combinatorial library comprising a predetermined collection of nucleoside peptide molecules for inhibiting the transfer of a sugar from a selected sugar nucleotide donor to a selected acceptor by a carbohydrate processing enzyme (e.g., see figure 1 and compounds listed therein; see also page 802, column 1, paragraph 1, "The polyoxins are a group of closely related peptidyl nucleoside antibiotics produced by species of *Streptomyces*"; see also column 2, middle paragraph, "In order to increase the stability of synthetic polyoxins toward intracellular hydrolysis we modified the backbone and chain ends of the dipeptidyl nucleoside"; see also page 805, paragraph 2, "the polyoxins we have synthesized are either dipeptidyl or tripeptidyl uridine nucleoside derivatives"; see also page 802, column 1, paragraph 3, "dipeptidyl antibiotic analogues were strongly inhibitory to chitin synthetase [i.e., a carbohydrate processing enzyme that adds monomers to form the polymeric chitin]"; see also "Inhibition of Chitin Synthetase by Novel Polyoxins" section on page 302) wherein a nucleoside peptide molecule comprises (a) a nucleoside monomer (e.g., see top of figure 1 disclosing two nucleosides) (b) a spacer monomer coupled to the nucleoside monomer

wherein the spacer monomer comprises one or more amide linked amino acid residues or mimetics thereof (e.g., see figure 1, compound 4 wherein the NH-CH(butyl)-CO represents the amino acid and/or mimetic; see also compound 5 wherein the NH-CH(isobutyl)-CO- represents the amino acid and/or mimetic, etc.) and (c) cap monomers attached to the spacer monomer (e.g., see figure 1, compound 4 wherein the a methyl group caps the NH; see also compound 5 wherein a propyl group caps the NH) wherein the nucleoside peptide molecules differ from each other as to the identity of at least one element of the nucleoside monomer, spacer monomer, or cap monomers (e.g., see above where different spacers, caps, etc. are disclosed). Please note that Shenbagmurthi et al. do not explicitly state that chitin synthetase is a carbohydrate processing enzyme but the Examiner contends that this is an inherent feature of chitin synthetase as exemplified by Spindler et al, which refers to the enzyme as a UDP-N-acetylglucosamine-glycosyltransferase (e.g., see Spindler et al., page 287, column 1, paragraph 4, note 2).

For *claims 2 and 3*, Shenbagmurthi et al. do not explicitly state that their library members can be used to inhibit “glycosyltransferase involved in the biosynthesis of glycoproteins, glycolipids, or glycosyl phosphatidyl inositols.” However, Shenbagmurthi et al. do disclose Applicants’ most preferred structures (e.g., see claims 18 and 19 below) and further disclose that these compounds will inhibit an N-acetylglucosamine-glycosyltransferase as set forth in claim 3. Therefore, Shenbagmurthi et al. inherently disclose this feature. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.

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1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For **claim 4**, Shenbagamurthi et al. teach a combinatorial library as claimed in claim 1 wherein the nucleoside monomer is, for example, uridyl (e.g., see figure 1, compounds 4 and 5)

For **claim 5**, Shenbagamurthi et al. teach a combinatorial library as claimed in claim 1 wherein the cap monomer is, for example, methyl (e.g., see figure 1, compound 4 wherein the NH is covalently attached to a methyl group).

For **claim 6**, Shenbagamurthi et al. teach a combinatorial library as claimed in claim 1 wherein the spacer monomer is a single amide linked amino acid an amide linked dipeptide or an amide linked tripeptide or a mimetic thereof (e.g., see figure 1, compound 4 wherein norleucine is disclosed).

For **claim 18**, Shenbagamurthi et al. teach, for example, compound 4 that falls within the scope of claim 18 wherein Z' and Z = OH, X = COOH, R = norleucine (i.e., an amide linked amino acid) and the free amine of the norleucine is capped with a methyl group. Likewise, compound 5 falls within the scope of claim 18 where Z' and Z = OH, X = COOH, R = 5-methyl-norleucine (i.e., an amide linked amino acid) and the free amine of the 5-methyl-norleucine is capped with a propyl (i.e., alkyl) group.

For **claim 19**, Shenbagamurthi et al. teach, for example, compound 4 that falls within the scope of claim 19 wherein X = COOH, Z' and Z = OH, R = NHCOR¹ wherein

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$R^1 = \text{CHR}^3\text{R}^4$ and $R^3 = \text{NH}_2$ and $R^4 = \text{butyl}$ (i.e., alkyl) and the free amino is capped with methyl.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
June 7, 2007

JON EPPERSON
PRIMARY EXAMINER

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